## REMARKS

The applicants appreciate the Examiner's detailed consideration of pending claims 1-49 in the application. Reconsideration of the rejections set forth in the Office action mailed April 5, 2005 is respectfully requested, in view of the following amendments and remarks.

I. Amendments

Independent claims 1, 18, 37 and 42 have been amended to delete the phrase "under reaction conditions effective to inhibit esterification of said hydrolyzed phospholipid with released fatty acids". Dependent claims 6 and 24 are amended accordingly, and a similar amendment is made in independent claims 29 and 47.

Typographical errors are corrected in claims 4, 23 and 32.

Claims 37-49 are cancelled without prejudice, to expedite prosecution of the remaining claims. The applicants reserve the option to pursue this subject matter in a continuing application.

No new matter is added by any of the amendments.

II. Claim Objections

The typographical error noted in claim 4 has been corrected.

With respect to claims 6 and 24, applicants note that each of these claims recites that the "second enzyme is effective to *selectively* hydrolyze said triglyceride"; the italicized term is not present in the parent claims. The definition of an enzyme which is "selective for lipase activity" is given at paragraph 0077 of the specification, which states that "the degree of hydrolysis of acyl glycerols [e.g., triglycerides, diglycerides, and/or monoglycerides] by the lipase is greater than the degree of hydrolysis of acyl phospholipids by the lipase." This distinguishes such an enzyme from, for example, a lipase which hydrolyzes both phospholipids and triglycerides, with low or no selectivity. Accordingly, the claims are further limited over the parent claims.

III. Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-28 and 37-49 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had

possession of the claimed invention.

Specifically, claims 1, 18, 37, 42, and their dependent claims were rejected in view of the phrase "reaction conditions effective to inhibit esterification of said hydrolyzed phospholipid with released fatty acids". While that applicants do not agree that such conditions are not described in the specification, the phrase has been deleted to expedite prosecution.

IV. Rejections under 35 U.S.C. §112, First Paragraph

Claims 4, 5, 15, 22, and 23 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification in such a manner as to enable one skilled in the art to make and use the invention without undue experimentation.

The Examiner states (pages 3-4 of Office Action) that "Phospholipases A1 or A2 do not hydrolyze the phosphatidyl component of the phospholipid; phospholipases A1 and A2 hydrolyze the ester bonds between the glycerol backbone and the acyl side chains; applicants calls this hydrolysis of the triglyceride."

This statement reflects an apparent misinterpretation of the language of the claims and specification, which seems to be reflected in a large number of the current rejections.

None of the claims, in fact, refer to hydrolyzing "the phosphatidyl component of the phospholipid". Independent claim 1, for example, states (emphasis added):

"(a) contacting **a lecithin material, comprising a phospholipid component and a triglyceride component**, in an aqueous or organic solvent medium, with a first enzyme, said enzyme being a phospholipase or lipase effective to **hydrolyze said phospholipid**; and

(b) subsequently contacting the product of step (a) with a second enzyme, different from said first enzyme, said second enzyme being a lipase effective to **hydrolyze said triglyceride**".

The Examiner has apparently interpreted a "lecithin material" to refer to a phospholipid molecule, and the "phospholipid component" and "triglyceride component" to refer to different portions of the molecule.

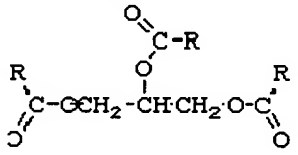
This is not what is intended by the applicants. As stated in the applicants' specification at, for example, paragraph 0026, "Lecithins...comprise a **mixture of phospholipids and triglycerides**" (emphasis added). Accordingly, "phospholipids" refers to one type of compound, and "triglycerides" to another type of compound. Both are "components" of the lecithin "mixture".

This usage is consistent with usage elsewhere in the specification, e.g. at paragraphs 0046 ("...a crude lecithin material, typically containing about 60-65% phospholipids (acetone insolubles), with the remainder primarily glycerides..."), 0048 ("In the two-enzyme process of the invention, a phospholipase (or a phospholipid reactive lipase) is used to hydrolyze phospholipids in the lecithin starting material to lysophospholipids and/or phosphatidic acids, and a separate lipase is used to hydrolyze triglycerides to mono/diglycerides."), and 0039 ("the invention provides a hydrolyzed lecithin product, containing phospholipids and/or hydrolyzed phospholipids, monoglycerides, and diglycerides. The product may also contain triglycerides.")

This usage is also consistent with the widely accepted meaning of the term "triglyceride" (as well as "diglyceride" and "monoglyceride") in the art, in which these terms refer to esters of glycerol with fatty acids, not with phosphatidic acids.

For example, the IUPAC "Recommendations on Organic & Biochemical Nomenclature, Symbols & Terminology", available at http://www.chem.qmul.ac.uk/iupac/, provides the following definitions of these terms:

**glycerides**: Esters of glycerol (propane-1,2,3-triol) with *fatty acids*, widely distributed in nature. They are by long-established custom subdivided into triglycerides, 1,2- or 1,3-diglycerides, and 1- or 2-monoglycerides, according to the number and position of acyl groups (not, as one might suppose, the number of glycerol residues). The recommended method for naming individual glycerides is mono-, di- or tri-*O*-acylglycerol, as appropriate. BNRD, Rule Lip-1.2(b) (p. 181).


(a triglyceride)

Definitions from other sources include the following (with emphasis added):

**triglyceride** n. A naturally occurring ester of *three fatty acids* and glycerol that is the chief constituent of fats and oils.
**diglyceride** n. An ester of *two fatty acids* and glycerol.
Source: The American Heritage® Dictionary of the English Language, Fourth Edition
Copyright © 2000 by Houghton Mifflin Company.

**triglyceride** n. See triacylglycerol.
**triacylglycerol** n. A naturally occurring ester of *three fatty acids* and glycerol that is the chief constituent of fats and oils. Also called triglyceride.
Source: The American Heritage® Stedman's Medical Dictionary
Copyright © 2002, 2001, 1995 by Houghton Mifflin Company.

**triglyceride**: any of a number of naturally occurring lipids formed when *three fatty acids* replace the three hydrogen atoms in the hydroxyl groups of glycerol, having the general formula $CH^2(OOCR_1)CH(OOCR_2)CH_2(OOCR_3)$ and representing the chief constituent of fats and oils, including the fat cells in the human body.
**diglyceride**: a fat composed of a glycerol molecule attached to *two fatty acids*; its emulsifying property is useful as an additive for shortenings and other food products.
**monoglyceride**: a compound consisting of *one molecule of fatty acid* esterified to a glycerol group.
Academic Press Dictionary of Science and Technology; 1992 Academic Press, Inc.

Accordingly, the applicants' usage of these terms is consistent with the standard usage in the art, in which "triglycerides", "diglycerides", and "monoglycerides" refer to esters of glycerol with fatty acids, not with phosphatidic acids.

In view of the above, an enzyme "effective to hydrolyze said phospholipid" can be an enzyme which hydrolyzes any bond in the phospholipid molecule, and is not limited to hydrolysis of certain portions of the molecule.

In view of the foregoing, the applicants submit that the pending claims comply with the requirements of 35 U.S.C. §112, first paragraph.

V. Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1-49 were rejected under 35 U.S.C. §112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 1, 18, 37, 42, and their dependent claims were rejected in view of the phrase "reaction conditions effective to inhibit esterification of said hydrolyzed phospholipid with released fatty acids". While applicants disagree that such conditions are not described in the specification, the phrase has been deleted to expedite prosecution.

In addition, claims 1, 4, 5, 14, 15, 18, 22 and 23 were rejected as unclear, in view of the terms "phospholipid component" and an enzyme effective to hydrolyze the phospholipid. The Examiner surmised that the "phospholipid component" referred to a portion of the phospholipid molecule, and further surmised that the "triglyceride component" referred to another portion of the phospholipid molecule.

This issue is addressed in detail in Section IV, above. As noted therein, the specification

states, at paragraph 0026, that "Lecithins...comprise a **mixture of phospholipids and triglycerides**" (emphasis added). Accordingly, "phospholipids" refers to one type of compound, and "triglycerides" to another type of compound. Both are "components" of the lecithin "mixture". As also discussed above, one skilled in the art would generally understand the term "triglyceride" (or diglyceride or monoglyceride) to refer to an ester of glycerol with fatty acid(s), and not to a portion of a phospholipid molecule.

The typographical error noted in claim 23 has been corrected, and the phrase objected to in claim 29 has been deleted.

In view of the foregoing, the applicants submit that the pending claims comply with the requirements of 35 U.S.C. §112, second paragraph.

VI. Rejections under 35 U.S.C. §102(b)

Claims 18 and its dependent claims 19, 22 and 24 were rejected under 35 U.S.C. §102(b) as being anticipated by Pardun, U.S. Patent No. 3,652,397. This rejection is respectfully traversed for the following reasons.

A. The Claims

Independent claim 18 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aprotic organic solvent, with first and second enzymes, wherein said first enzyme is a phospholipase or lipase effective to hydrolyze said phospholipid, and said second enzyme, different from said first enzyme, is a lipase effective to hydrolyze said triglyceride.

B. The Prior Art

The Examiner states that the reference discloses contacting a lecithin material as recited in the claims, with first and second enzymes as recited in the claims, in an aprotic organic solvent.

However, the reference states that the hydrolysis "is conveniently carried out...in the presence of at least 25 percent, and preferably at least 50 percent of **water**, by weight of the phosphatide..." (col 3, lines 1-3), and that the "crude partially hydrolyzed vegetable phosphatide(or hydrolysate) obtained is **then** subjected to **extraction** with a solvent suitable for separation of free fatty acids...preferably the direct product of hydrolysis (containing the water

present during hydrolysis) is used for the extraction" (col 2, lines 11-17) (emphasis added). The working examples also describe the phosphatide "slime" being in water during addition of the enzyme; after reaction, the water content is reduced, and the mixture is washed or extracted with an organic solvent. (See col 3, lines 20-24 and 31; lines 61-70 and following.) There is no description of a "phosphatide" in an organic solvent being contacted with an enzyme.

Since the reference does not disclose all of the elements set out above in claim 18 and its dependent claims, the claims cannot be anticipated by this reference under 35 U.S.C. §102(b). In view of this, the applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §102(b).

VII. Further Rejections under 35 U.S.C. §102(b)

Claims 29-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Haas *et al.*, *J. Am. Oil Chem. Soc.*, **71**(5):483-490 (1994). Claim 29 was also rejected as being anticipated by VanMiddlesworth *et al.*, *J. Org. Chem.* **57**:4753-4 (1992). These rejections are respectfully traversed for the following reasons.

A. The Claims

Independent claim 29 is directed to a method of producing a hydrolyzed lecithin product, comprising phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, and in the absence of a phospholipase, with a lipase effective to selectively hydrolyze said triglyceride.

B. The Prior Art

The Haas *et al.* reference describes enzymatic hydrolysis of phosphatidyl choline (PC). This substance is described in the "Materials" section (page 483, column 2) as "L-α-PC" with >99% purity.

The VanMiddlesworth *et al.* reference describes enzymatic hydrolysis of "a dried sample of soybean phosphatidyl inositol **2** (40 mg, .049 mmol)" (page 4754, first column); the compound **2** is also identified as "1-stearoyl (or palmitoyl)-2-linoleoyl-3-glycero-phosphatidyl-D-myo-inositol (**2**)" (Page 4753, first column), and its structure is shown in Scheme I.

The starting materials in these reactions are clearly shown to be essentially pure phospholipid; there is no indication that any triglyceride is present. Accordingly, neither

reference discloses "contacting a lecithin material, comprising a phospholipid component and a triglyceride component...with a lipase", as recited in the claims.

Since the references do not disclose all of the elements set out above in claim 18 and its dependent claims, the claims cannot be anticipated by either reference under 35 U.S.C. §102(b). In view of this, the applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §102(b).

VIII. Rejections under 35 U.S.C. §103(a)

Claim 1 and its dependent claims 4-7, 11, 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sas *et al.*, U.S. Patent No. 6,068,997, in view of Hattori *et al.*, U.S. Patent No. 5,378,623. The rejections are respectfully traversed in light of the following remarks.

A. The Claims

Independent claim 1 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising:

(a) contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, with a first enzyme, said enzyme being a phospholipase or lipase effective to hydrolyze said phospholipid; and

(b) subsequently contacting the product of step (a) with a second enzyme, different from said first enzyme, said second enzyme being a lipase effective to hydrolyze said triglyceride.

Accordingly, the process is a two-step process, and employs a different enzyme in each step. As described in the specification at paragraph 0049, the use of a two-stage process is advantageous especially in aqueous media, where "reaction of the lipase to selectively hydrolyze triglycerides can lead to a large increase in the viscosity of the medium." Accordingly, "the lecithin starting material is first contacted with the phospholipase (or phospholipid reactive lipase) enzyme, and, after sufficient time for reaction and, optionally, recovery of an intermediate product, subsequently contacted with the (triglyceride selective) lipase enzyme."

B. The Cited Art

Sas *et al.* describes hydrolysis of "lipids and phospholipids of crude lecithin" (col 1, lines 37-38) using a blend of enzymes, e.g. lipase and phospholipase A2 (col 2, line 58). The reference emphasizes that the hydrolysis of the components is "simultaneous" and is carried out

"in a single step" (col 1, lines 37, 41, 47; col 2, lines 11, 31, 36). There is no suggestion of any benefit to be gained by using a multistep process, which would normally be considered less convenient.

Hattori *et al.* describes a phospholipase A1 isolated from *Aspergillus*. As noted at col 1, lines 24-26, "selective hydrolysis of a phospholipid substrate with a phospholipase A1 produces a 2-acyl lysophospholipid". The particular enzyme disclosed is said to have various advantages over prior art enzymes such as pancreatin, e.g. ease of deactivation and pH range of activity (col 3, lines 49-57). Reactions using the enzyme may be carried out in aqueous or organic solvents (col 12, lines 6-9 and 20-26). However, there is no disclosure of using multiple enzymes, either simultaneously or sequentially, in a hydrolysis process.

Because neither reference teaches or suggest the sequential use of two different enzymes to hydrolyze a composition containing both phospholipids and triglycerides, or the advantages of such a process, independent claim 1 and its dependent claims would not have been obvious over this combination of references.

In view of the foregoing, the applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §103(a).

IX. Further Rejections under 35 U.S.C. §103(a)

Claim 1 and its dependent claims 8-10, 16 and 17; claim 23 and its dependent claims 27 and 28; dependent claims 35-36, and product claims 37-49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sas *et al.*, U.S. Patent No. 6,068,997, in view of Hattori *et al.*, U.S. Patent No. 5,378,623, Haas *et al.*, *J. Am. Oil Chem. Soc.*, 1994, and Chung *et al.*, U.S. Patent No. 6,773,902. The rejections are respectfully traversed in light of the following remarks.

A. The Claims

Independent claim 1, as described in Section VIII above, is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising:

(a) contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, with a first enzyme, said enzyme being a phospholipase or lipase effective to hydrolyze said phospholipid; and

(b) **subsequently** contacting the product of step (a) with a second enzyme, **different** from said first enzyme, said second enzyme being a lipase effective to hydrolyze said triglyceride.

Independent claim 18 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an **aprotic organic** solvent, with first and second enzymes, wherein said first enzyme is a phospholipase or lipase effective to hydrolyze said phospholipid, and said second enzyme, **different** from said first enzyme, is a lipase effective to hydrolyze said triglyceride.

Claim 35 is directed to a method of producing a hydrolyzed lecithin product, comprising phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, and in the **absence of a phospholipase**, with a lipase effective to selectively hydrolyze said triglyceride;

wherein said hydrolyzed lecithin product comprises at least 56% acetone insoluble materials and has an acid value of less than 45 mg KOH/gram.

As noted above, claims 37-49 have been cancelled to expedite prosecution of the remaining claims.

B. The Cited Art

Sas *et al.*, as discussed above, describes hydrolysis of "lipids and phospholipids of crude lecithin" using a blend of enzymes, e.g. lipase and phospholipase A2. The reference teaches that the disclosed method gives significantly higher conversion rates than prior art processes for enzymatic hydrolysis of phospholipids (e.g. page 1, fourth paragraph; page 3, second paragraph).

The reference emphasizes that the hydrolysis of the lecithin components is "simultaneous" and carried out "in a single step". There is no suggestion of any benefit to be gained by employing a multistep process.

The solvent mixture employed in Sas *et al.* is repeatedly and specifically described as "a water/polyol mixture" or "an aqueous/polyol environment". Neither solvent is "aprotic".

Hattori *et al.*, as discussed above, describes a phospholipase A1 isolated from *Aspergillus*, which selectively hydrolyzes phospholipids to 2-acyl lysophospholipids. The patent states that the "enzyme or substrate solution is suitably aqueous" (column 12, lines 6-7). Although the subsequent paragraph states that the reactions may also be carried out in organic solvents, all of the working examples employ water or aqueous buffers as solvents.

Haas *et al.* describes enzymatic hydrolysis of >99% purity phosphatidyl choline (PC), using each of three different lipases, in solvents of different polarities. (Although the abstract refers to eight enzymes, it goes on to state that only three had appreciable phospholipase activity.) As shown in Fig. 1, the general trend observed was that activity decreased with decreasing solvent polarity, although addition of water tended to offset this effect.

Chung *et al.* describe the preparation of high purity lysophosphatidyl ethanolamine by enzymatic hydrolysis of phosphatidyl ethanolamine, or of a different phospholipid in the presence of ethanolamine, using phospholipase A2. The reactions are carried out in "water or organic solvents" (col 4, lines 35-37); the working examples typically employ 1:1 ethyl acetate/aqueous buffer or 1:1 diethyl ether/aqueous buffer.

C. Analysis

Claim 1: Of the above cited references, only one (Sas *et al.*) describes or suggests hydrolysis of a composition containing both phospholipids and triglycerides (i.e., "comprising a phospholipid component and a triglyceride component").

Haas *et al.* describes a study of the reaction of several specific enzymes with a phospholipid molecule; adding triglycerides to the reaction mixture would defeat the purpose of the study. The same can be said of Chung *et al.*, which is directed to production of "high purity" lysophosphatidyl ethanolamine.

Finally, none of the above reference teaches or suggest the sequential use of two different enzymes to hydrolyze such a composition containing both phospholipids and triglycerides, or the advantages of such a process. Accordingly, independent claim 1 and its dependent claims would not have been obvious over this combination of references.

Claim 18: Again, of the above cited references, only one (Sas *et al.*) describes or suggests hydrolysis of a composition containing both phospholipids and triglycerides, by using a lipase

and a phospholipase in combination.

Even though Haas *et al.* and Chung *et al.* show that such enzymes could show activity "in an aprotic organic solvent", for hydrolysis of phospholipids alone, Haas et al. show variable results for the use of lipases in such solvents. Sas *et al.* repeatedly and specifically describe the solvent to be used for their process as "a water/polyol mixture" or "an aqueous/polyol environment". Sas *et al.* teach that the disclosed method gives significantly higher conversion rates than prior art processes for enzymatic hydrolysis of phospholipids (e.g. page 1, fourth paragraph; page 3, second paragraph). Accordingly, one skilled in the art would not be motivated by the disclosures of the other cited references to change the solvent used in Sas *et al.* to an "aprotic organic solvent".

Claim 35: Again, of the above cited references, only one (Sas *et al.*) describes or suggests hydrolysis of a composition containing both phospholipids and triglycerides (i.e., "comprising a phospholipid component and a triglyceride component"). Haas *et al.* describes a study of the reaction of several specific enzymes with a phospholipid molecule; adding triglycerides to the reaction mixture would defeat the purpose of the study. The same can be said of Chung *et al.*, which is directed to production of "high purity" lysophosphatidyl ethanolamine.

Furthermore, only Haas *et al.* describes the use of a lipase "in the absence of a phospholipase", and this was done in order to determine how such enzymes (lipases) would react with a phospholipid molecule (phosphatidyl choline). As stated in the abstract, only three of eight enzymes tested showed appreciable activity towards the phospholipid. In view of this, there would have been no motivation to carry out the method of Sas *et al.* "in the absence of a phospholipase", since the purpose in Sas *et al.* was to hydrolyze both phospholipids and triglycerides, and the reference emphasizes the use of two enzymes for this purpose.

Accordingly, independent claim 35 and its dependent claims would not have been obvious over this combination of references.

X. Further Rejections under 35 U.S.C. §103(a)

Claims 2, 3, 11 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sas *et al.*, U.S. Patent No. 6,068,997, in view of Hattori *et al.*, U.S. Patent No. 5,378,623, Haas *et al.*, *J. Am. Oil Chem. Soc.*, 1994, and Chung *et al.*, U.S. Patent No. 6,773,902, and further in

view of Jirjis *et al.*, US Pubn. No. 2003/0072856. The rejections are respectfully traversed in light of the following remarks.

A. The Claims

Claims 2-3 further limit independent claim 1, described above, by reciting that the phospholipid component makes up at least 50% or at least 60%, respectively, of the lecithin starting material.

Claim 11 further limits independent claim 1, described above, by reciting that the lecithin material is a retentate from a vegetable oil membrane degumming process.

Claim 13 further limits independent claim 1, described above, by reciting that the solvent comprises an organic solvent (intervening claim 8) and that steps (a) and (b) are carried out in the presence of a membrane effective to separate hydrolyzed phospholipids, monoglycerides, and diglycerides from released fatty acids.

B. The Cited Art

Each of Sas *et al.*, Hattori *et al.*, Haas *et al.* and Chung *et al.* is discussed above in Section IX. The application of this combination of references to independent claim 1 is described in Section IX.C above. As stated therein, only Sas *et al.* describes hydrolysis of a composition "comprising a phospholipid component and a triglyceride component"; the remaining references do not suggest such a process. Sas *et al.* provides no motivation to employ two different enzymes sequentially, as claimed, rather than simultaneously, in hydrolyzing such a composition.

Jirjis *et al.* describes methods for membrane processing of vegetable oil miscella. An organic solvent such as hexane is generally employed, and "intermediate" solvents are used to condition the membrane. Phospholipids are selectively removed from the miscella to give a primary product (filtrate) which is enriched in oils (i.e. triglycerides) and reduced in phospholipids.

As noted at paragraph 0054 in Jirjis *et al.*, the retentate stream, containing the removed phospholipids, "can be processed into a lecithin product 136 by devolatilizing the solvent". Possible modifications of this lecithin product are described very generally at paragraph 0056. However, the reference clearly provides no suggestion to employ two different enzymes sequentially, as claimed, to hydrolyze any kind of phospholipid-containing composition.

Accordingly, claim 1 and its dependent claims should be found patentable over this

combination of references.

XI. Further Rejections under 35 U.S.C. §103(a)

Independent claim 18 and its dependent claims 19-22 and 24-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Pardun *et al.*, U.S. Patent No. 3,652,397, in view of Jirjis *et al.*, US Pubn. No. 2003/0072856. The rejections are respectfully traversed in light of the following remarks.

A. The Claims

Independent claim 18 is directed to a method of producing a hydrolyzed lecithin product, comprising hydrolyzed phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an **aprotic organic** solvent, with first and second enzymes, wherein said first enzyme is a phospholipase or lipase effective to hydrolyze said phospholipid, and said second enzyme, **different** from said first enzyme, is a lipase effective to hydrolyze said triglyceride.

B. The Cited Art

Pardun describes "partial hydrolysis of a vegetable phosphatide with an enzyme preparation containing lipase and phospholipase A" (Abstract). As discussed above in Section VI, the reaction is carried out in a mixture of the phosphatide and water, and the product is then extracted with an organic solvent. There is no description of a phosphatide in an organic solvent being contacted with an enzyme.

Jirjis *et al.*, as discussed above in Section X, describes methods for membrane processing of vegetable oil miscella. An organic solvent such as hexane is generally employed, and "intermediate" solvents are used to condition the membrane. Phospholipids are selectively removed from the miscella to give a primary product (filtrate) which is enriched in oils (i.e. triglycerides) and reduced in phospholipids.

As noted at paragraph 0054 in Jirjis *et al.*, the retentate stream, containing the removed phospholipids, "can be processed into a lecithin product 136 by devolatilizing the solvent". Accordingly, the "lecithin product", of which possible modifications are described generally at paragraph 0056, is solvent-free, and there is no description of what solvent(s) should be employed to carry out such modifications.

C. Analysis

In view of the comments above, neither of these references provides any teaching or suggestion to carry out enzymatic hydrolysis of a lecithin product, using first and second enzymes, in an aprotic organic solvent.

Accordingly, claim 18 and its dependent claims should be found patentable over this combination of references.

XII. Further Rejections under 35 U.S.C. §103(a)

Dependent claims 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over either Haas *et al.*, *J. Am. Oil Chem. Soc.*, 1994, or VanMiddlesworth *et al.*, *J. Org. Chem.* **57**:4753-4 (1992), in view of Jirjis *et al.*, US Pubn. No. 2003/0072856. The rejections are respectfully traversed in light of the following remarks.

A. The Claims

Independent claim 29 (not cited) is directed to a method of producing a hydrolyzed lecithin product, comprising phospholipids, monoglycerides, and diglycerides, the method comprising:

contacting a lecithin material, comprising a phospholipid component and a triglyceride component, in an aqueous or organic solvent medium, and in the absence of a phospholipase, with a lipase effective to selectively hydrolyze the triglyceride.

Dependent claim 31 recites that the lecithin material is a retentate from a vegetable oil membrane degumming process.

Dependent claims 32-33 recite that the phospholipid component makes up at least 50%, or at least 60%, respectively, of the lecithin material.

Dependent claim 31 recites that the contacting is carried out in the presence of a membrane effective to separate the phospholipids, monoglycerides, and diglycerides from released fatty acids.

B. The Cited Art

Haas *et al.*, as discussed above in Section IX, describes enzymatic hydrolysis of >99% purity phosphatidyl choline (PC), using each of eight different lipases, in solvents of different polarities.

VanMiddlesworth *et al.*, as discussed above in Section VII, describes enzymatic hydrolysis of "a dried sample of soybean phosphatidyl inositol **2** (40 mg, .049 mmol)"; the compound **2** is

also identified as "1-stearoyl (or palmitoyl)-2-linoleoyl-3-glycero-phosphatidyl-D-myo-inositol (**2**)", and its structure is shown in Scheme I of the article.

The starting materials in these reactions are clearly shown to be essentially pure phospholipid; there is no indication that any triglyceride is present. Haas *et al.* describes a study of the reaction of several specific enzymes with a phospholipid molecule; adding triglycerides to the reaction mixture would defeat the purpose of the study. The same can be said of VanMiddlesworth *et al.*, which is directed to semisynthetic production of a particular phospholipid molecule. Accordingly, neither reference discloses or suggests "contacting a lecithin material, comprising a phospholipid component and a triglyceride component...with a lipase", as recited in the claims.

Jirjis *et al.* describes methods for membrane processing of vegetable oil miscella, where phospholipids are removed via membrane separation, to give a primary product enriched in oils (i.e. triglycerides) and reduced in phospholipids. An organic solvent such as hexane is generally employed, and "intermediate" solvents are used to condition the membrane.

As noted at paragraph 0054 in Jirjis *et al.*, the retentate stream, containing the removed phospholipids, can be processed into a lecithin product. Possible modifications of the product are described at paragraph 0056: "The lecithin product according to the invention can be used as a starting material for derived processes and products, such as, deoiled lecithin, phospholipids fractions, enzymatical modifications, chemical modifications, and compounded products. Exemplary chemical modifications include hydroxylation, acetylation, interesterification, and hydrogenation. Exemplary compounded products include use on a carrier and with emulsifiers."

This very general description of a broad range of modifications provides no motivation to employ a lipase, "in the absence of a phospholipase", to hydrolyze the phospholipid-enriched product. As noted above, the other cited references are clearly not concerned with hydrolysis of triglycerides in a phospholipid/triglyceride mixture.

Accordingly, claim 29 and its dependent claims should be found patentable over this combination of references.

XIII. Further Rejections under 35 U.S.C. §103(a)

Independent claims 37, 42 and 47 and dependent claims 39, 41, 44, 46 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over 't Hooft *et al.*, US Pubn. No. 2002/0122867.

As noted above, these claims have been cancelled to expedite prosecution of the remaining claims. Accordingly, this rejection is rendered moot.

XIV. Conclusion

In view of the foregoing, the applicant submits that the claims now pending are now in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4403.

Respectfully submitted,

Date: Sept-6, 2005

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